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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/993,976

11/05/2001

Milton B. Yatvin

99,297

7958

20306

7590

02/26/2004

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/993,976	Applicant(s) YATVIN ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

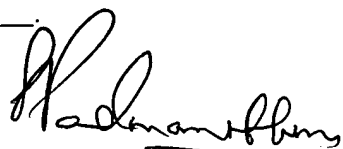
Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-11, 18 and 19.

Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


SREENI PADMANABHAN 2/22/04
SUPERVISORY PATENT EXAMINER

Advisory Action

This Office Action is a response to Applicant's proposed amendment and response after FINAL filed on January 8, 2004.

2. Applicant's proposed amended claims herein, "wherein the pharmaceutical composition does not comprise a polar lipid" is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the negative limitation, and also present a new issue for search and consideration by the Examiner.

Applicant is requested to note that any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

5. Applicant's remarks filed January 8, 2004 with respect to all prior art rejections:

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the rejection of Claims 1, 3-5, 7-9 and 18 made under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,149,794) for reasons of record stated in the Final Office Action dated October 2, 2003;

the rejection of claims 1-5, 7-9, 11 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,543,389) for reasons of record stated in the Final Office Action dated October 2, 2003;

the rejection of claims 1-5, 7-9, 11 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al. (US 5,827,819) for reasons of record stated in the Final Office Action dated October 2, 2003;

the rejection of Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference by Yatvin et al. (US 5,149,794) for reasons of record stated in the Final Office Action dated October 2, 2003, have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated October 2, 2003. Thus, all prior art rejections maintained.

Thus, the obviousness-type double patenting rejection of Claims 1, 3-5, 7-9 and 18 as being unpatentable over claims 1-10 of U.S. Patent No. 5,149,794, the obviousness-type double patenting rejection of Claims 1-5, 7-9, 11 and 18-19 as being unpatentable over claims 1-27 of U.S. Patent No. 5,543,389, and the obviousness-type double patenting rejection of Claims 1-5, 7-9, 11 and 18-19 as being unpatentable over claims 1-12 of U.S. Patent No. 5,827,819 for reasons of record stated in the Final Office Action dated October 2, 2003, are maintained.

Again, Applicant's argument that the structure recited as being an "amino acid derivative" is in fact a peptide, tBc-NH-A1a-A1a- or Gly-G1y-G1y-G1y-NH, as understood by one having ordinary skill in the art. This definition is also inconsistent with the explicit definition of "an amino acid derivative" in the instant specification at page 17 lines 11-17, is not found convincing. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

Moreover, Applicant's argument that Yatvin (US 5,149,794) does not disclose compositions having amino acids or amino acid derivatives, attached to a drug, that are specifically transported into a physiologically-protected site, as claimed. Yatvin teaches embodiments that are: drug-amino acid-lipid or drug-peptide-lipid, while the present invention teaches drug-amino acid or drug-amino acid derivative.

It is noted that the transitional phrases "comprising" is employed in the instant claimed composition. Applicant is requested to note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. The specific structure by the specific order and arrangement, i.e., represent by a structural formula, is not recited in the claims.

As discussed in the Final Office Action, Yatvin (US 5,149,794) discloses a pharmaceutical composition comprising an antiviral or an anti proliferative or

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antineoplastic drug, a polar lipid carrier, and two linker functional groups and a spacer, wherein the spacer has a first end and a second end and wherein the amino acid or amino acid derivative i.e., tBc-NHAla-Ala- or -Gly-Gly-Gly-Gly-NH-, is attached to the first of the spacer through a first linker functional group and the drug is attached to the second end of the spacer through a second linker functional group (see particularly Fig.1-8; Examples 1-8; claims 1 and 7). Moreover, Yatvin clearly discloses that the instant spacer is a peptide for (amino acid)_n formula, a polymer of a particular amino acid (see claim 6 in particular) i.e., tBc-NHAla-Ala- or -Gly-Gly-Gly-Gly-NH-. The teachings of In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 12, 2004



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/22/04